Remarks

Independent Claims 1 and 14 have been amended in line 1, after the word "comprising" to claim the invention resides in a combination of elements which act in concert and that such a combination in itself is a distinctive and indivisible functional entity and the elements also interact or cooperate with each other.

Applicant submits that the insertions are not new matter and merely make explicit that what is explicit in the application as filed.

Claims 1 and 14, as currently filed have been amended to specifically state the specific conditions of the method for conditioning an industrial product, the specific conditions for sterilizing the said product, the specific conditions for degassing the product, and specific steps completed to validate process parameters which render evidence of appropriate lethality and residual reduction to the industrial product.

Basis for the amendments appear in the specification on pages 1-9, with special emphasis on the Summary, the Detailed Description and Example 1 on pages 6-8 wherein steam is used as a degassing gas wash injection

Rejection of Claims Under 35 U.S.C. § 102(a)

Claims 1-4, 6 and 13 are rejected by the Examiner under 35 U.S.C. § 102(a) as being anticipated by Popescu et al (U.S.P.N. 5,464,580).

Regarding claim 1, the Examiner notes that Popescu teaches the following steps in ethylene sterilization of medical items (col. 1, lines 6-11); conditioning items by placing them into a chamber then evacuates the chamber, then introduces steam, then re-evaluates again (col. 5, lines 22-32), injecting ethylene gas into the chamber (col. 5, lines 40-41), introducing an overpressure nitrogen gas into the chamber (col. 5, lines 37-40), holding the items in the chamber until sterilization is reached (col. 5, lines 43-45) and degassing the items (col. 6, lines 35-44).

Regarding claims 2-4, 6 and 13, the Examiner notes that Popescu teaches the following: heated inert gas is nitrogen (col. 5, lines 54-56), sterilant is ethylene gas (col. 5, lines 40-41), evacuating the chamber after holding the product in the chamber (col. 5, lines 49-51) and pulsing in heated inert gas into the chamber (col. 6, lines 12-35), degassing the items by evacuating the chamber (col. 6, lines 19-21), pressurizing the chamber with 3 to 50 inches of mercury with nitrogen gas (21-22), repeating until the items are degassed (col. 6, lines 19-32) and the rate of degassing is in the range of 0.1 to 0.5 inches per minute (col. 6, lines, 27-28, 0.83 K/min is equivalent to 0.24 inches of mercury (min).

Applicant respectfully traverses and requests reconsideration and re-examination of claims 1-4, 6 and 13 as amended.

Applicant respectfully brings to the Examiner's attention that the instant application is directed to a method for sterilizing products using ethylene oxide wherein the entire sterilization process which consists of conditioning, sterilization and degassing the product or article is performed in a single chamber, page 2, lines 19-23.

Applicant respectfully brings to the Examiner's attention that, as amended, Claim 1 claims a precise method of monitoring the moisture content of the method by injection of pulsed stream into the single chamber to increase chamber pressure by at least 2 inches of mercury and thus adds moisture to the chamber.

Applicant respectfully notes that Popescu '580 teaches the sterilization process includes multiple containment vessels or chambers, col.3, lines 1-5, and that the system of Popescu '580 is a closed system, col. 3, lines 5-10, to maintain an aseptic condition, whereas the instant process claimed is performed in a single chamber.

Applicant respectfully brings to the Examiner's attention that the instant process comprises a degassing step wherein a gas wash comprising a number of steam injections is an alternative method of degassing, Example 1, Gas Wash A, lines 27-34. no of repeats 4 (5 total).

Applicant respectfully notes that Popescu '580 transfers the products of the '580 process to a drying chamber 18 to eliminate residual ethylene oxide and moisture from the sterilized product, col. 6, lines 8-11, to prevent degradation of the product.

Applicant accordingly respectfully submits that Claims 1-4, 6 and 13, as amended, are not anticipated by Popescu, U.S. Patent 5,464,580 under 35 U.S.C. § 102(a). Applicant respectfully submits that the constitute anticipation, all of the material claimed elements must be found within the four corners of a single prior art reference (In re Outrup, 189 USPQ 345). Applicant respectfully submits that Popescu '580 does not teach, suggest or anticipate within the four corners of the reference all the material claimed elements of the instant invention.

The claimed elements of the instant invention, as provided in the amended independent Claims 1 and 14 and dependent claims, as amended, are as follows:

a) the use of a single chamber;

b) the injection of steam and N_2 as separate gas wash injections in the degassing steps as gas washes in a number of separate steam injections and separate N_2 injections;

c) the specific elements recited in the amended Claims 1 and 14, and the dependent claims, which are claimed as a combination, which act in concert and that such combination is itself a distinctive and indivisible functional entity and that the individual elements also interact and cooperate with each other.

Applicant accordingly respectfully submits that the instant invention uses steam as a degassing element which Popescu '580 does not teach, suggest or infer within the four corners of the reference. Popescu '580 teaches only use of nitrogen gas (col. 5, lines 37-59) and use of a drying chamber 18 to eliminate moisture (col. 6, lines 12-35).

Applicant accordingly respectfully submits that Popescu '580 teaches away from what is claimed and taught in the instant application. Applicant uses different process parameters including steam to accomplish the degassing step and therefore the instant invention permits the use of a single chamber.

The conditioning step can be performed without pulsing inert gas but only using steam, page 4, lines 2-3. The steam is pushed and pulled out of the chamber repeatedly until the load is at the desired temperature and the humidity is at the desired level. The different process parameters of the instant invention permit different procedures that are adjustable to different conditions. For example, Popescu '580 uses steam to humidify the product, col. 5, lines 26-30, but the instant invention uses steam as a process element for other then humidifying the product.

Rejection of Claims Under 35 U.S.C. § 103

Applicant respectfully notes that for a reference to be prior art under 35 U.S.C. § 103 there must be some basis for concluding such reference would have been considered by one skilled in the art working on the problem to which the invention pertains. There must be some teaching, at least suggestion, in the prior art that the individual elements can, or should, be combined as claimed in the claimed invention. In re Demarche, 105 USPQ 193, 200; Smith Kline Diagnostics, Inc. v. Helena Laboratories Corp. 8 USPQ 2d 1468, 1475.

Claims 14-16 are rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Popescu, et al, U.S. patent 5,464,580 in view of Vera U.S. Patent 6,440,364 and further in view of Joslyn U.S. Patent 4,770,851.

Applicant respectfully submits that the test for obviousness under 35 U.S.C. § 103 is there must be some basis for concluding such reference would have been considered by one skilled in the art and working on the problem. Applicant submits that Popescu '580 teaches away from the process of the instant invention, which uses steam to degass the product after sterilization whereas Popescu '580 uses only dry gasses.

Regarding Claim 14 it is the position of the Examiner that Popescu teaches the following steps in ethylene sterilization of medical items (col. 1, lines 6-11): conditioning items by placing them into a chamber, then evacuate the chamber, then introduce steam, then re-evacuate again (col. 5, lines 22-32), injecting ethylene gas into the chamber (col. 5, lines 40-41), introducing an overpressure nitrogen gas into

the chamber (col. 5, lines 37-40) at a pressure of 13 inches of mercury (col. 5, lines 38-40), holding the items in the chamber until sterilization is reached (col. 5, lines 43-45), evacuating the chamber to vacuum pressure values less than 1-3 inches of mercury and pulsing in heated nitrogen into the chamber (col. 5, lines 53-55). Popescu fails to teach evacuating to pressure of to 3 inches of mercury and injecting the chamber with warm air.

Applicant respectfully notes that after sterilization is complete Popescu fails to teach application of steam as a degassing element but only teaches a drying chamber 18 and use of dry nitrogen gas, col. 6, lines 5-35.

The Examiner notes that Vera teaches evacuating to a pressure of 1 to 3 inches of mercury (col. 3, lines 46-48) and injecting filtered air into the chamber (col. 5, lines 5-11). Therefore, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by evacuating the chamber to pressure of 1 to 3 inches of mercury to provide an effectively low pressure sufficient to effectively remove air from the chamber (Vera, col. 3, lines 44-46) and to flush the chamber with filtered air in order to perform the degassing cycle into separate chambers (Vera, col. 5, lines 1-7).

Applicant respectfully traverses and requests reconsideration and reexamination of claim 14, as amended.

Applicant respectfully submits that Vera is evacuating a first chamber to a pressure of 1 to 3 inches of mercury, col. 3, lines 46-48 in the initial step in the sterilization process, col. 3, lines 38-50. After the sterilization procedures, the sterilant product is subject to air washing and a final vacuum prior to degassing. Degassing is conducted in a separate conventional degassing chamber, col. 5, lines 1-7.

Applicant respectfully submits that the instant application teaches and claims a single chamber for all the steps of sterilization, holding the product, introducing an over-pressure, degassing the product, and releasing the product from the single chamber wherein a conventional degassing chamber is not used as Vera requires.

Applicant therefore submits that it would not have been obvious to one of ordinary skill in the art to further modify the Popescu method to copy the Vera method by further modifying the Popescu method to provide an effectively low pressure sufficient to effectively remove air from the chamber (Vera, col. 3, lines 44-46) and to flush the chamber with filtered air in order to perform and move the degassing cycle into separate conventional chambers (Vera, col. 5, lines 1-7) when Popsescu '580 teaches the use of an inert gas instead of air to reduce the possibility of an explosive mixture (col. 5, lines 56-60).

The Examiner notes that Vera teaches injecting filtered air into the chamber (col. 5, lines 5-11), but fails to teach injecting warm air. Joslyn teaches injecting warm air into the chamber (col. 6, lines 40-43). It is the position of the Examiner that as a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by adding a heated air injection step as taught by Joslyn in order to insure that the residual concentration of ethylene oxide is kept to minimum within the sterilized load at the shortest possible time (Joslyn, table 2, columns 3-4).

Applicant respectfully traverses and requests reconsideration and re-examination of Claim 14, as amended.

Applicant respectfully submits that Joslyn measures residual concentration of ethylene oxide by gas chromatographic evaluation which requires a gas chromatographic unit not previously suggested, inferred or indicated as being a necessary element to properly sterilize an industrial product by Popescu '580.

Applicant respectfully submits that the instant application teaches and claims a process for sterilizing and degassing a product to validated process parameters which render to the product specific product and process evidence of appropriate level of lethality and residual reduction. Applicant notes the preferred method of measuring concentration of ethylene oxide in the subject process is disclosed in U.S. Patent Application No. 10/361,508 which is incorporated by reference. The preferred method uses a microwave generator and a tuning cavity (page 5, lines 18-20).

Applicant notes that any procedure commonly used to provide evidence of appropriate level of lethality and residual reduction such as chromatographic analysis would be expected to be used without being an element of the sterilizing process.

Applicant therefore submits that it would not be obvious to one of ordinary skill in the art to further modify the process of Popescu '580 by adding a heated air injection step to permit gas chromatographic analysis to insure the residual concentration of ethylene oxide is kept to a minimum as an additional step when a specific teaching or inference or suggestion to do so is not expressed, taught or implied to replace a preferred method as taught on page 5, lines 18-20.

Regarding Claim 15, it is the position of the Examiner that Popescu discloses that the evacuating rate during the degassing cycle is in the range of 0.1 to 0.5 inches per minute (col. 6, lines 27-28, 0.83 Kpa/min is equivalent to 0.245 inches of mercury/min) but fails to teach evacuating to a pressure of 1 to 3 inches of mercury. Vera teaches evacuating to a pressure of 1 to 3 inches of mercury (col. 3, lines 46-48). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by evacuating to between 1 to 3 inches of mercury as taught by Vera in order to effectively remove air from the chamber and the package (Vera, col. 3, lines 44-46).

Applicant respectfully traverses and requests reconsideration and re-examination of Claim 15, as amended.

Applicant respectfully submits that Vera, col. 3, lines 46-48, teaches evacuating the chamber of the sterilization unit in the initial step in the process to remove air from the chamber and the package to a vacuum of from 1 K Pa A to about 10 K Pa A, followed by injection of humidity into the chamber by a steam source.

Applicant respectfully submits that the citation of Vera, col. 3, lines 46-48, refers to the initial step in the sterilization procedure whereas Popescu '580 discloses the cited evacuating rate is in the degassing cycle, whereas Claim 15 refers to the evacuating of the single chamber after placing the product to be sterilized in the chamber to be sterilized, before the initial step in the sterilization procedure.

Applicant respectfully submits that there is no suggestion, teaching or inference in Vera to suggest the modification of the initial evacuation of the chamber in the initial evacuation of the chamber since this procedure is suggested for application in the Popescu '580 degassing cycle instead of for the initial evacuation and that it would be obvious to one of ordinary skill in the art to modify the Popescu '580 degassing method to the procedure taught by Vera when there is no apparent reason to do so and relates to a different step in the overall cycle.

Regarding Claim 16 it is the position of the Examiner that Popescu teaches repeating the step of pulsing heated nitrogen into the chamber (col. 5, lines 54-56 and col. 6, lines 19-32).

Applicant respectfully submits that, as amended, Claims 1 and 14 claim the invention resides in a combination of elements which act in concert and that such combination in itself is a distinctive and indivisible functional entity and that the elements also interact or cooperate with each other.

Applicant respectfully traverses and requests reconsideration and reexamination of Claim 16.

Applicant respectfully submits that Claim 16 is an element in the combination of elements which comprise a distinctive and indivisible functional entity of the instant invention, which as an interacting and cooperating element in the process claims the step of pulsing steam and/or heated nitrogen into the single chamber of the process and is to be considered in the context of the combination.

Claims 5 and are rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580) as applied to Claim 4 and further in view of Vera et al (U.S.PN. 6,440,364), Stewart et al (U.S.P.N. 5,882,590) and Weber et al (U.S.P.N. 5,161,686). Applicant notes that the above rejection unstated of claims cannot be answered. The answer is directed to Claim 5.

It is the portion of the Examiner that Popescu fails to teach evacuating to a pressure of 1 to 3 inches of mercury and the use of real-time monitoring of headspace. Vera teaches evacuating to a pressure of 1 to 3 inches of mercury (col. 3, lines 46-48). Therefore, it would have been obvious to one of ordinary skill in the art the time the invention was made to further modify Popescu method by evacuating

to between 1 to 3 inches of mercury as taught by Vera in order to effectively remove air from the chamber and the package (Vera, col. 3, lines 44-46).

Applicant respectfully traverses and requests reconsideration and re-examination of claim 5 as stated above.

Applicant respectfully refers the Examiner to the above applicant's response to the Examiner's earlier rejection of Claim 14 based on Vera wherein the applicant's response also applies, as stated on pages 11-12 hereinabove.

It is the position of the Examiner that Vera fails to teach the use of real-time monitoring of headspace. Stewart teaches the use of real-time monitoring (col. 3, lines 19-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by adding real-time monitoring step as taught by Stewart so that the concentration of sterilant is maintained within the required range thereby guaranteeing efficient sterilization.

Applicant respectfully traverses and requests reconsideration and re-examination of Claim 5.

Applicant respectfully submits that the Examiner's suggestion to improve the sterilization process by other methods than commonly employed such as by indirect calculation of consumption, concentration and calculation of ethylene oxide gas in headspace and the procedure taught by U.S. Application No. 10/361,508 (page 4, lines 18-20) is appreciated. Applicant appreciates the suggestion to improve the real-time monitoring step to utilize the procedure as taught by Stewart, col. 3, lines 19-22, by employing semi-conductor based sensor modules to selectively detect and measure the actual sterilant concentration to control the critical environmental parameters to maintain concentration levels within acceptable levels.

Applicant respectfully submits that Popescu '580, Vera '364 and Stewart '590 did not teach, suggest or infer the adding real-time monitoring step as taught by Stewart was an obvious step at the time the invention was made and that the Popescu '580 method should be modified to include the Stewart '590 procedure.

Applicant therefore respectfully submits that other factors than the Examiner's fertile imagination at the time the invention was made would have suggested, taught or inferred that the Stewart procedure not be used to modify the Popescu '580 procedure such as availability of other commonly available procedures and methods already in use for measuring specific product parameters such as the procedure taught in U.S. Application No. 10/361,508, incorporated by reference (page 5, lines 18-20).

It is the position of the Examiner that Stewart fails to teach monitoring headspace that Weber teaches measuring headspace within web structures (col. 12, lines 56-62) and performing headspace analysis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by adding a headspace measurement step as taught by Weber in order to determine the absorbing abilities of various web materials (Weber, col. 12, lines 56-59) resulting in sterilizing materials more efficiently.

Applicant respectfully traverses and requests reconsideration and re-examination of Claim 5 in view of Popescu '580, Stewart '590 and Weber '686 in view of the above remarks.

As for Weber '686, Applicant respectfully submits that Weber '686 teaches and claims a medical product package containing a medical product adapted to be sterilized by gamma irradiation, the product formed from materials that emit odorous substances upon subjected the gamma irradiation and a web material adapted to absorb the odorous substances caused by gamma irradiation.

Appplicant respectfully submits that Weber teaches, col. 12, lines 56-62, the absorbing ability of various odor-absorbing materials for using a gas chromatography headspace analysis using a pyridine compound volatile mixture as a blank to ensure the presence of all components of the volatile mixture caused by gamma irradiation.

Applicant respectfully submits that the procedure of Weber '686 requires availability of gas chromatographic analytical equipment to measure headspace and the requirement of web structures to perform headspace analysis based on odors produced by gamma irradiation.

Applicant respectfully submits that Weber '686 teaches away from the teaching and claims of Popescu '580 in that there is no suggestion, teaching or inference in Popescu '580 that the Popescu '580 method to measure the headspace could be improved by use of the Weber '686 procedure using gamma irradiation and gas chromatographic analytical equipment and to use of various web materials as taught by Weber '686 to absorb the odorous products to produced by gamma irradiation.

Claims 10, 12, 11, 8 and 7, have been rejected by the Examiner as follows:

Regarding claim 10, it is the position of the Examiner that Popescu teaches degassing the items by evacuating the chamber, pressurizing the chamber with 29 inches of mercury with nitrogen and repeating the cycle (col. 6, lines 19-35).

Claim 12 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580), Vera et al (U.S.PN. 6,440,364), Stewart et al (U.S.P.N. 5,882,590), Weber et al (U.S.P.N. 5,161,686) as applied to claim 10 and further in view of Joslyn (U.S.P.N. 4,770,851).

As to Claim 12, it is the position of the Examiner that Vera teaches injecting filtered air into the chamber (col. 5, lines 5-11). However, Popescu, Vera, Stewart and Weber all fail to teach injecting warm air. Joslyn teaches injecting warm air into the chamber (col. 6, lines 40-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by adding a warm injection step as taught by Joslyn in order to insure that the residual concentration of ethylene oxide is kept to minimum within the sterilized load at the shortest possible time (Joslyn, table 2, columns 3-4).

It is the position of the Examiner that Claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580), Vera et al (U.S.PN. 6,440,364), Stewart et al (U.S.P.N. 5,882,590), Weber et al (U.S.P.N. 5,161,686) as applied to claim 5 and further in view of Kolstad et al (U.S.P.N. 4,973,449).

It is the position of the Examiner that Popescu, Vera, Stewart and Weber all fail to teach evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of

heated nitrogen gas. Kolstad teaches pulsing by evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas (col. 5, lines 30-36). Thus, it would have been obious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by including the pulsing process of Kolstad in order to subject the contents of the sterilization chamber to pressure differential pulses of significant magnitude in the presence of the biocidal chemical vapors (Kolstad, col. 5, lines 30-41) for the efficient sterilization of the contents.

It is the position of the Examiner that Claim 8 is rejected under 36 U.S.C. 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580) as applied to Claim 6 and further in view of Joslyn (U.S.P.N. 4,770,851).

Popescu fails to teach injecting warm air. Joslyn teaches injecting warm air into the chamber (col 6., lines 40-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method by adding a warm air injection step as taught by Joslyn in order to insure that the residual concentration of ethylene oxide is kept to minimum within the sterilized load at the shortest possible time (Joslyn, table 2, columns 3-4)

It is the position of the Examiner that Claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Popescu et al (U.S.P.N. 5,464,580) as applied to Claim 3 and further in view of Kolstad et al (U.S.P.N. 4,973,449).

Popescu fails to teach evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas. Kolstad teaches pulsing by evacuating the chamber down to 3 to 7 inches of mercury and pulsing the chamber with 5 to 9 inches of heated nitrogen gas (col. 5, lines 30-36). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Popescu method of including the pulsing process of Kolstad in order to subject the contents of the sterilization chamber to pressure differential pulses of significant magnitude in the presence of the biocidal chemical vapors (Kolstad, col. 5, lines 30-41) for more efficient sterilization of the contents.

Applicant respectfully submits that as to the rejection of Claims 10, 12, 11, 8 and 7 under 36 U.S.C. 103(a) as indicated by the Examiner above, that claims 10, 12, 11 and 8 relate to the procedure of the degassing step. Applicant respectfully submits that the subject matter of Popsesu '580 in view of Vera '365, Stewart '590, Weber '686, Joslyn '851 and Kolstad '449 teach away from the claimed subject of Claims 10, 12, 11 and 8 as amended and submitted herewith.

Applicant respectfully submits that as to the rejection of Claim 7 under 35 U.S.C. § 103(a), dependent Claim 7 relates to use of a single chamber being evacuated down to 3 to 7 inches of mercury and pulsing the said single chamber with 5 to 9 inches of heated inert gas in the degassing procedure. As a dependent claim, Applicant notes Claim 7 is subject to the limitations of Claim 1.

Applicant respectfully submits that Popescu '580 as the primary reference teaches away from the teachings of Popsescu '580, Vera '364, Stewart '590, Weber '686 as applied to Claim 10, Claim 12, Claim 11, Claim 8, and Claim 7 in that Claims 7, 8, 10, 11, 12 relate to the degassing procedure. The elements of degassing as taught and claimed by the instant application teach and claim the use of steam separately and in conjunction with dry, inert gas which is contrary to the teaching and claims of Popescu '580. Applicant therefore respectfully submits that Popescu '580, Vera '364, Stewart '590, Weber '686, teach away from the process and method of the instant invention and that Claims 7, 8, 10, 11, 12 are not obvious under 35 U.S.C. § 103 as indicated by the recited position of the Examiner as indicated above.

Respectfully submitted,

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